BBS-Bioactive Bone Substitutes – Insider information: The company updates the status of the CE marking process

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Based on the available information, the company estimates that the CE marking process will not be completed by the end of the second quarter in 2024 as previously estimated. The process is at a stage where the company has submitted the required information for product registration to the authorities.

During these final phases of the process, the company will no longer provide an exact time estimate for the completion of the CE marking process, as the company can no longer influence the processing schedules of the authorities.

The product's journey towards commercialization (updated)

Phase	Action	Status
Product development	Preclinical animal tests	Completed
	Functionality and efficiency tests	Completed
	Clinical test	Completed
CE marking	Submitting the CE application	Completed
	Quality system application	Approved
	1st audit	Completed
	2nd audit	Completed
	Additional audit	Completed
	Additional measures	Completed
	Product approval	In process
	Product classification	Completed
	Consultation with the Medicines Agency	In process
	Production lines and line certification	In process
Commercialization	Preliminary commercialization	In process
	Extensive commercialization	In preparation

Previously published announcements related to the CE marking application

- November 25, 2023 – The Notified Body has approved the Company’s quality system
- November 2, 2023 – Insider information: The company provides an update on the CE marking process related to the approval of the quality system – consultation with the Finnish Medicines Agency to begin on 21 November 2023

- September 13, 2023 – Insider information: Plan to complete minor open issues approved – the Company updates its outlook on the schedule of the CE marking
- August 31, 2023 – Inside information: The final report of the additional audit received from the Notified Body
- May 26, 2023 – Inside information – Positive decision received on the product classification, schedule for the quality system approval to be updated
- March 27, 2023 – Inside information: The final report of the second audit received from the Notified Body, the CE marking process may continue and CE marking approval continues to be expected during 2023
- December 30, 2022 – Insider information: BBS updates the estimate of the CE marking approval schedule of ARTEBONE® Paste
- November 18, 2022 – Inside information: The first audit completed by the Notified Body, CE marking process may continue as planned
- March 9, 2022 – BBS Bioactive Bone Substitutes Plc has filed the CE-marking application of Artebone® bone void filler to the authorities

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BBS in brief
BBS -Bioactive Bone Substitutes Plc is an orthobiology company that started its operations in 2003. We have developed a new product for the treatment of complex bone fractures and bone healing issues. Our goal is to provide next-generation medical products for the treatment of bone injuries in orthopedic surgery. In the pharmaceutical industry, the development and research work require perseverance and courage to innovate. We have a track record of over 20 years in this field. Our company is characterized by expertise, innovation, and dedicated employees who are passionate about their work. Our first developed product, ARTEBONE® Paste, is in the final stages of the CE marking process to enable its commercialization in the EU market. We are based in Oulu with a medical manufacturing facility in Reisjärvi, holding a manufacturing license. The company's headquarters are in Oulu, and we employ over 20 people.

BBS has been listed on Nasdaq First North Growth Market Finland since February 2018.

More information: www.bbs-artebone.fi